510(k) Summary
As required by 21CFR 807.92

OCT 16 2012

510(k) Number:	K121805
Date Prepared:	August 29, 2012
Submitter's Name/ Address:	American Medical Systems 10700 Bren Road W. Minnetonka, MN 55343
Contact Person:	Laura Moen-Ftacek Principal Regulatory Affairs Specialist Tel: 952-930-6426 Fax: 952-930-5785 Laura.Moen-Ftacek@AmericanMedicalSystems.com
Alternate Contact:	Melanie Hess Director, Regulatory Affairs Tel: 952-939-6094 Fax: 952-930-5785 Melanie.Hess@AmericanMedicalSystems.com
Device Information:	
Trade Name:	IntePro® Y-Mesh
Common Name:	Surgical Mesh
Classification Name:	Mesh, surgical, synthetic, urogynecologic, for apical vaginal and uterine prolapse, transabdominally placed
Class:	Class II / 21 CFR § 878.3300
Product Code:	OTO

Predicate Device:

IntePro® AMS Large Pore Polypropylene Mesh (K040521)

Device Description:

The IntePro® Y-Mesh is constructed of polypropylene suture (fibers) knitted together to form a mesh. The mesh has bi-directional elasticity and resists unraveling. The mesh is provided as a sterile, single use device in a pre-formed Y-shape for sacrocolpopexy procedures.

Indications for Use:

The IntePro® Y-Mesh is intended for use in vaginal prolapse repair via abdominal sacrocolpopexy procedures, including but not limited to open, laparoscopic, and robotically assisted surgical approaches.

Summary of the Technical Characteristics to the Predicate Device(s):

All technical characteristics of the proposed device are identical to those of the predicate, including device design, materials of construction, manufacturing process and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 16 2012

Ms. Renee Mellum
Senior Regulatory Affairs Associate
American Medical Systems
10700 Bren Road West
MINNETONKA MN 55343

Re: K121805
Trade/Device Name: IntePro® Y-Mesh
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTO
Dated: October 1, 2012
Received: October 3, 2012

Dear Ms. Mellum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121805

Device Name: IntePro® Y-Mesh

Indications for Use: The IntePro® Y-Mesh is intended for use in vaginal prolapse repair via abdominal sacrocolpopexy procedures, including but not limited to open, laparoscopic, and robotically assisted surgical approaches.

Prescription Use ___X___ AND/OR Over-The Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121805